

APPENDIX

DECLARATION OF BIOMATERIALS ENGINEER AND CO-INVENTOR TIMOTHY A. RINGEISEN

I, Timothy A. Ringeisen, declare and say as follows:

That I am an inventor named on U.S. Patent Application Serial No. 10/729,146, entitled "Compressed High Density Fibrous Polymers Suitable for Implant";

That I am named as an inventor or co-inventor on 4 issued U.S. Patents and 13 pending U.S. patent applications;

That my formal education consists of a Bachelor of Science degree in Biology from Gustavus Adolphus College, and a Master of Industrial Hygiene from University of Minnesota;

That the above-identified patent application is subject to an obligation of assignment to Kensey Nash Corporation, a Delaware corporation with facilities in Exton, Pennsylvania;

That I am employed by Kensey Nash Corporation at its Exton facility as a Director of Biomaterials Research;

That I have 6 years experience with this company, and that I have 17 years experience overall as a Biomaterials Engineer;

That I am familiar with U.S. Patent No. 5,158,574 to Stone, and with U. S. Patent Application Publication No US2002/0127270 A1 to Li et al.;

That I am familiar with the invention claimed in the above-identified USSN 10/729,146 patent application;

That the claimed invention relates to a compressed polymeric fibrous implant where the fibers are at least partially aligned and arrange themselves in the form of plates or layers of aligned fibers;

That the partially aligned fibers of the instant invention may be prepared by charging a slurry featuring liquid, fibers and a lubricant into a mold, and compressing the slurry to remove fluid;

That as compression commences, the fibers migrate through the remaining fluid and begin to organize themselves into a plurality of layers or plates. The fibers tend to align within a given layer or plate, but the layers or plates themselves are not necessarily aligned with respect to one another. The layers or plates are defined by fluid planes. The fluid planes may not extend across the entire structure, but instead may exist as multiple fissures located randomly throughout the structure. Additional compression brings the layers or plates of fibers into closer contact, allowing them to become locked into a compact anisotropic structure, although the material may be isotropic in two dimensions.

That Stone prepares a prosthetic, resorbable meniscus for implantation in a human knee, and in one embodiment thereof, he aligns fibers in a circumferential direction by rotating a mold as the fibers are placed in the mold, or by compressing the fibers in a mold with a rotating piston.

That the circumferential orientation of the fibers in Stone is due to the rotation of the piston or mold, according to Stone himself;

That the rotation of the piston or mold disrupts any plate or layer formation;

That the compression process of the instant invention never features a rotation of a piston or of the mold during the compression step;

That the respective fabrication processes (i.e., Stone versus that of the present application) are fundamentally different from one another;

That the arrangement of fibers in the respective products is likewise fundamentally different from one another;

That Li prepares an oriented biopolymeric membrane by depositing a slurry containing fibers onto a rotating mandrel, and then compressing the deposited fibers to remove excess fluid;

That the rotation of the Li mandrel disrupts any plate or layer formation;

That it is the rotating mandrel of Li and not the compressing of the deposited fibers that orients the fibers in Li;

That by the time Li compresses his deposited fibers, they are already oriented;

Thus, the fiber orientation mechanism in Li is different from that of the instant invention;

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Amdt. Dated April 23, 2007
Reply to Final Office Action of January 22, 2007

That the compression process of the instant invention never features a rotation of a mandrel during the compression step;

That the respective fabrication processes (i.e., process of Li versus that of the present application) are fundamentally different from one another;

That the arrangement of fibers in the respective products is likewise fundamentally different from one another; and

That I understand that all statements made herein (including statements made in the attachment documents) of my own knowledge are true and that statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Further, declarant sayeth not.

Timothy A. Ringeisen
Timothy A. Ringeisen

18 April 2007
Date